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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,173	04/08/2004	Susan R. Webb	TSRI 536.1 C1	3667

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

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05/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,173	WEBB ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-60,85-91 and 100-153* is/are pending in the application.

4a) Of the above claim(s) *34,37,38,41,85-91,100-140 and 151-153* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35,36,39,40,42-60 and 141-150* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20041122*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/715,231, which is a divisional of U.S. Application Serial Number 09/194,285, which is a rule 371 continuation of PCT Serial Number PCT/US97/08697, which claims the benefit of the filing date of provisional U.S. Application 60/018,175.

Claims 1-32, 61-84, and 92-99 have been canceled.

Claims 114-153 were previously added.

Claims 33-60, 85-91 and 100-153 are currently pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 33-60 and 141-150, in the reply filed on February 16, 2007 is acknowledged.

Applicant's election without traverse of a "cell" as the species of matrix support in the reply filed on February 16, 2007 is acknowledged.

Applicant's election **with traverse** of a "costimulatory molecule," more specifically B7.1, as the species of accessory molecule in the reply filed on February 16, 2007 is acknowledged. Upon further review this particular species election requirement has been withdrawn.

1. Claims **85-91, 100-140 and 151-153 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected invention**, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 16, 2007.

Claims **34, 37, 38 and 41 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected species**, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 16, 2007.

Accordingly, **claims 33, 35, 36, 39, 40, 42-60 and 141-150 are the subject of examination** in the present Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 33, 35, 36, 42-60 and 141-150 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,355,479 (A on form PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed "synthetic antigen presenting matrix" is inclusive of cells and the synthetic Drosophila antigen presenting cells of the '479 patent fall within the scope of the instant claims, as the cells of the '479 patent possess both MHC class II extracellular domains as well as the instantly recited accessory molecules.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 33, 35, 36, 39, 40, 42-44, 46, 48, 50, 51, 53, 54, 56, 58, and 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for accessory molecules selected from the costimulatory molecules B7.1 and B7.2, the adhesion molecules ICAM-1, ICAM-2, ICAM-3, LFA-1 and LFA-3 and the survival molecules Fas ligand, TNF receptor and CD70, does not reasonably provide enablement for other types of accessory molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are most broadly drawn to a "synthetic antigen presenting matrix" comprising the extracellular portion of Class II MHC molecule and an "accessory molecule." The instant specification discloses the accessory molecules B7.1, B7.2 (costimulatory molecules), ICAM-1, ICAM-2, ICAM-3, LFA-1, LFA-3 (adhesion molecules), Fas ligand, TNF receptor and CD70 (survival molecules). Beyond the disclosed elements, the term "accessory molecule" encompasses any molecule which may participate in the processes of antigen processing and/or presentation, including all molecules which have a role from capture and uptake of an antigenic molecule by the matrix to internal molecules (as the "matrix reads upon an intact cell) which chaperone the antigen or break up larger proteins into epitope peptides, molecules which assist the association of the epitope with the Class II molecule and cytokines which stimulate the activation of reactive T cells, as all such molecules perform accessory functions to MHC class II. The specification does not teach molecules which participate in all aspects of antigen processing and presentation and therefore does not provide sufficient guidance to one of ordinary skill in the art to practice the claimed invention commensurate in scope with the recitation of "accessory molecules."

Furthermore, a "teaching" in the specification of generic accessory molecules does not provide any information regarding the functionality of any of those generic molecules, nor does it provide any structural information to the artisan about the structural features of the generic molecules or how those generic molecules interact with the matrix/T cell interaction or with the antigen processing pathway. Exemplifying eight accessory molecules provides information only about those eight molecules and is not reasonably predictive of the artisan's success in incorporating other types of accessory molecules into the claimed synthetic matrix.

In view of the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and the statute does not sanction this.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 149 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 149 is ambiguous and unclear in the recitation of "the at least one accessory molecule is B7.1 and B7.2." While the claim encompasses having more than one accessory molecule, a single accessory molecule cannot be two different molecules simultaneously.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 33, 35, 36, 42, 44-60 and 141-150 are rejected under 35 U.S.C. 102(b) as being anticipated by Banuls et al (Immunology [1993] 79:298-304; U on form PTO-892).

Applicant is reminded that the claims are to be interpreted with their broadest reasonable interpretation. Base claim 33 recites that the claimed invention is drawn to a "synthetic antigen presenting matrix for activating CD4+ T cells." According to the specification, and as evidenced by claim 35, the claimed matrix is inclusive of intact cells. the claim also recites that the matrix comprises "an extracellular portion of a recombinant MHC class II heterodimer" and "at least one recombinant accessory molecule." The terms "synthetic" and "recombinant" refer to methods of making the matrix and molecules. The terms do not convey and structural properties of the matrix or molecules that would distinguish them from naturally produced products. In other words, the claimed "synthetic" matrix can be identical to a naturally produced matrix and the "recombinant" MHC class II heterodimer and accessory molecules can be identical to a naturally produced MHC class II heterodimer and accessory molecules. Accordingly, the claims are drafted in a product by process manner. If the same product can be made by another process, the product is still the same, irrespective of the manner in which it is produced. Therefore, given their broadest reasonable interpretation, the claims read upon a naturally produced antigen presenting cell because a dedicated antigen presenting cell inherently comprises MHC class II and the MHC class II heterodimer inherently comprises the extracellular portion of the heterodimer. In addition, a dedicated antigen presenting cell inherently possesses the costimulatory molecules B7.1 and B7.2; the adhesion molecules ICAM-1, ICAM-2, ICAM-3, LFA-1 and LFA-3; and the survival molecules Fas ligand, TNF receptor and CD70.

Banuls teaches the antigen presenting matrix represented by rat dendritic cells. Banuls specifically teaches that the rat dendritic cells express MHC class II on their surface, as well as the accessory molecules B7.2 (OX48), LFA-1 and ICAM-1. While Banuls does not specifically teach any "survival molecules" on the rat dendritic cells, silence about a particular property does not necessitate its absence. Furthermore, it is well known that the presence of such molecules on the surface is an inherent property of dendritic cells. The prior art teaching anticipates the claimed invention.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
May 11, 2007

DAVID A. SAUNDERS
PRIMARY EXAMINER